

**PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA (PhRMA)
Submission for the Record
Hearing on U.S.-India Trade Relations:
Opportunities and Challenges
March 13, 2013**

The House Ways and Means Trade Subcommittee hearing on U.S. – India trade relations takes place at an opportune time. Chairman Nunes, Ranking Member Rangel, and the members of the subcommittee should be praised for holding their first trade hearing of this Congress on India.

The title of the hearing, “U.S.-India Trade Relations: Opportunities and Challenges”, aptly describes the Indian market. However, at this time it seems to be tipping more to challenges.

The deteriorating protections for patented medicines in India have become increasingly concerning to PhRMA and its member companies. Over the past year, the Government of India has issued several intellectual property (IP) decisions that have disproportionately impacted U.S. biopharmaceutical companies. The Government of India has created a protectionist regime that harms U.S. job creators. The harm is evident in our industry, where the U.S. has welcomed Indian companies while India is closing its borders to U.S. innovators. For instance, three of India’s largest pharmaceutical companies have generated around 50% of their revenue in the U.S.¹ Experience accumulated after India began granting product patents in 2005, shows it has routinely flouted trade rules to bolster local industry.

Our industry’s experience demonstrates that patent rights in India are unreasonably denied. Just last month (and for the second time in six months) the Indian Patent office revoked a patent on Sutent®, a cancer therapeutic, which is patented in over 90 countries around the world. Indian law also contains a discriminatory special rule for certain chemical and biological inventions. Using this rule, India refused patent protection for a breakthrough anticancer therapeutic (Glivec®) that enjoys patent protection in countries across the globe.

The Indian government has also sought to justify a compulsory license, in part, on the basis that the product was imported rather than manufactured locally. This blatant industrial policy must be repudiated as it plainly contravenes established international obligations.

Correcting India’s protectionist IP regime will require firm leadership by the United States in international organizations and in India. We urge Congress to work with the Administration to press the Government of India to step back from its industrial policies and give American companies the same market access that Indian companies enjoy in the U.S. We believe that working together with the Government of India we can ensure that patients in India and around the world will be able to benefit from our member companies’ innovative therapies.

¹ Press Release, Dr. Reddy’s Q1 FY13 Financial Results, July 19, 2012, available at http://www.drreddys.com/media/popups/q1fy13_results_19jul2012.html; Press Release, Sun Pharma reports a strong quarter, Aug. 10, 2012, available at <http://www.sunpharma.com/images/finance/FY13%20Q1%20Press%20Release%20Financials.pdf>; Press Release, Q1 FY13, Aug. 10, 2012, available at [http://www.wockhardt.com/pdf/QUARTERLY-REPORT-\(Q1\)-f12ee.pdf](http://www.wockhardt.com/pdf/QUARTERLY-REPORT-(Q1)-f12ee.pdf) (last visited Mar. 22, 2013).

Few industries provide more high-quality, high-paying, and high-productivity jobs in the United States than the biopharmaceutical sector. Industry employment (direct, indirect, and induced) in 2009 totaled 4.0 million jobs,² including direct employment of over 674,000 Americans.³ Direct employment in the biopharmaceutical sector grew almost twice as fast as employment in the rest of the economy between 1998 to 2008.⁴ Each job in the biopharmaceutical sector contributed more than double the average contribution to GDP from jobs in the rest of the economy.⁵ For every dollar that biopharmaceutical companies contributed to gross domestic product (GDP) in 2008, the ripple effect of that activity supported another \$1.91 in contribution to GDP from other sectors.⁶ Nevertheless, our industry faces tremendous loss of revenue that has been widely attributed to fallout of the Global financial crisis, including the deep austerity measures in Europe, threatening jobs, slowdowns in research and development, loss of exports, increased pressure to outsource, and more.⁷

At the same time, PhRMA member companies make substantial investments in research and development, further fueling the U.S. economy and advancing public health through the discovery and development of new cures and treatment options for patients. In 2011, PhRMA members alone invested \$49.5 billion in research and development for new medicines, almost 80 percent of which was invested in the United States.⁸ Furthermore, the average biopharmaceutical company spends approximately \$105,000 on R&D per direct employee, more than ten times the average R&D spend per employee in manufacturing industries overall.⁹ Moreover, according to the most recent data from the National Science Foundation, the U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing nearly 20 percent of all domestic R&D funded by U.S. businesses.¹⁰ These figures highlight the pressing need to defend this sector's IP rights against infringement. With more medicines in development in the United States than in the rest of the world combined, the United States accounts for approximately 3,240 products in development in 2011, in large part due to IP protections and other strong incentives that foster the environment needed to support continued research and development investment.¹¹

PhRMA and its member companies recognize that India has legitimate concerns regarding access to healthcare throughout the country and we acknowledge the challenges of the Government to make essential medicines available to the most vulnerable sections of society. However, we are concerned about inadequate IP

² Battelle Technology Partnership Practice, *The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation*, July 2011. Battelle Memorial Institute. Prepared for the Pharmaceutical Research and Manufacturers of America. (Battelle Report).

³ Id.

⁴ Id.

⁵ Id.

⁶ Id.

⁷ Id.

⁸ Sources including PricewaterhouseCoopers, *Exploring the Relationship between Revenues and Employment in the Biopharmaceutical Industry*, PwC Research Report, June 2009, Table 1; and Ryan, B., Deutsche Bank, "4Q'10 Review & Model Book," Feb. 14, 2011; Peterson, T, J.P. Morgan, "Pharma R&D Post-Mortem," Feb. 16, 2011.

⁹ PhRMA Annual Member Survey (Washington, DC: PhRMA, 2012).

¹⁰ Pham, N., *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs Wages, and Exports*, NDP Consulting (April 2010), available at http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf (last visited Mar. 22, 2013).

¹¹ Science and Engineering Indicators 2012, National Science Foundation, Division of Science Resource Statistics. 2012.

¹² Adis R&D Insight Database, Wolters Kluwer Health (accessed 10 Feb. 2012).

protections, including the recent issuance of a compulsory license, which pose significant market access barriers in India. Having created a strong domestic biopharmaceutical industry, India has so far failed to provide regulatory data protection to encourage new innovations carried out by both its own industry and PhRMA member companies. Further, standards for patentability need to be amended to conform to prevailing international practice.

Limiting IP protections and creating barriers to market access will only inhibit India's own biopharmaceutical industry from developing products for India, while doing little to improve accessibility of medicines for its population. Sustainable solutions to India's healthcare concerns should be found through programs that address the lack of healthcare financing. PhRMA and its member companies are willing to partner with the Indian Government in developing those public policy solutions.

Key Issues of Concern in India:

- **Compulsory Licensing (CL):** In March 2012, India issued its first CL.¹² The decision was based on price differences and Indian "patent working" requirements. The decision held that local manufacturing is mandatory to fulfill working requirements, which is not consistent with India's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Additionally, recent media reports indicate that the Government of India has started the process of issuing CLs for the manufacture of three additional cancer drugs.
- **Lack of Regulatory Data Protection:** The Indian Regulatory Authority relies on test data submitted by originators to another country when granting marketing approval. This indirect reliance results in unfair commercial use prohibited by the TRIPS Agreement and discourages the development of new medicines that could meet unmet medical needs.
- **Patent Enforcement and Regulatory Approval:** Indian law permits state regulatory authorities to grant marketing approval for generic versions of medicines four years after the product was first marketed. They are not required to consider the remaining term of the relevant patents.
- **Narrow Standards for Patentability:** Indian law also contains a prohibited, discriminatory "special" rule for certain chemical and biological inventions, which requires innovators to prove their product has "enhanced efficacy" to secure a patent. Additionally, the Indian Government recently revoked a patent on a cancer therapeutic using a "hindsight" analysis citing a lack of inventiveness.

Compulsory Licenses on Patented Pharmaceutical Products

India issued a compulsory license (CL) for an anti-cancer patented pharmaceutical product on March 9, 2012. We understand that this is the first CL issued

¹² Decision and Order on the Application for Compulsory Licenses under Section 84(1) of the Patents Acts, 1970 in Respect of Patent No. 215,758, March 2012.

in India. In addition, recent reports indicate that the Indian Government has started the process of issuing CLs for the manufacture of three additional anti-cancer medicines. Unlike the CL issued under Section 84 of the Patent Act in March, these CLs would fall under Section 92 of the Act – the public emergency provision that can be issued directly from the Indian Administration without a notice and comment period to the industry. The research-based pharmaceutical industry is concerned that the findings in the CL decision on the local working requirements are at odds with India's TRIPS commitments (as well as its broader WTO obligations), and distorts what was intended as a public health exception into an industrial policy. We further believe that resorting to CLs is not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by our member companies better ensure that current and future patients have access to innovative medicines. We are also concerned about apparent inaccuracies and misunderstandings that appear to underpin the reasoning reflected in the decision. For example, statements from the Government incorrectly imply that CLs are widely used by other governments (both, developed and developing), including the United States and Italy.¹³ Those inaccuracies and misrepresentations cannot justify resorting to compulsory licensing.

India should ensure that the CL provisions comply with TRIPS by clarifying that importation satisfies the "working" requirement (as required by TRIPS Article 27.1). In cases of CL for exports, India should ensure that, consistent with the August 30, 2003 Decision of the TRIPS Council on Implementation of Paragraph 6 of Doha Declaration on TRIPS Agreement and Public Health, proper anti-diversion measures are taken and that the CL is granted only for export to eligible importing countries that lack manufacturing capacity and used in good faith to protect public health and not used for industrial or commercial purposes.

Lack of Regulatory Data Protection

TRIPS Article 39.3 requires India to provide protection for certain pharmaceutical test and other data, but India has not yet done so. India conditions the approval of pharmaceutical products on the prior approval by a Regulatory Authority in another country rather than requiring submission of the entire dossier for review by its Regulatory Authority. An applicant in India needs only to prove that the drug has been approved and marketed in another country and submit confirmatory test and other data from clinical studies on a very few (in some cases as few as 16) Indian patients.

By linking approval in other countries that require the submission of confidential test and other data to its own drug approval process, India, in effect, uses those countries as its agents. Thus, India relies on test data submitted by originators to another country. This indirect reliance results in unfair commercial use prohibited by TRIPS.

¹³ These allegations of wide-spread use of CLs in the U.S. and the premise that CL's can resolve access problems in India have been refuted by OPPI and PhRMA. See http://dipp.nic.in/ipr-feedback/Feedback_OPPI_30September2010.pdf (last visited Mar. 22, 2013).

Patent Enforcement and Regulatory Approval

Indian law permits state drug regulatory authorities to grant marketing approval for a generic version of a new medicine after four years of patent protection for the new medicine. State regulatory authorities are not required to verify or consider the remaining term of the existing patent. Therefore, an infringer can obtain marketing authorization from the government for an on-patent drug, forcing the patent holder to seek redress in India's court system.

Moreover, India does not provide mechanisms for resolution of patent disputes prior to marketing approval of third party products. Such mechanisms are needed to prevent the marketing of patent infringing products. To ensure proper patent enforcement, the U.S. Government should urge the government to implement such mechanisms. Furthermore, PhRMA member companies report that even when their cases are filed in the Indian legal system, their ability to obtain redress for patent infringing product launches is extremely limited. We believe the Indian Government must also ensure that the existing laws and regulations can be properly enforced in a timely manner through its legal system.

Narrow Standards for Patentability

Some of the standards for patentability in India are not transparent and are inconsistent with the TRIPS Agreement. For example, section 3(d) of the Patents Act 1970 as amended by the Patents (Amendment) Act 2005 creates additional hurdles to the grant of certain chemical compound patents, and appears to be applied only to pharmaceuticals. Under this provision, salts, esters, ethers, polymorphs, and other derivatives of known substances are presumed to be the same substance as the original chemical and thus not patentable, unless it can be shown that they differ significantly in properties with regard to efficacy. These additional requirements for patentability beyond novelty, commercial applicability and non-obviousness are inconsistent with the TRIPS Agreement, in at least two respects. First, Article 27 requires that "patents shall be available for any inventions ... provided that they are new, involve an inventive step and are capable of industrial application." Although the TRIPS Agreement also provides a non-extendable list of the types of subject matter that can be excluded from patent coverage, this list does not include "new forms of known substances lacking enhanced efficacy" as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) is inconsistent with the framework provided by the TRIPS Agreement. Second, Section 3(d) represents an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, the Indian law is in conflict with the non-discrimination principle also provided by TRIPS Article 27. Moreover, from a policy perspective, Section 3(d) undermines incentives for innovation.

Another example of the overly narrow standards for patentability in India is the Government's recent revocation of a patent on a cancer therapeutic (a product that is patented in over 90 countries), using a "hindsight" analysis citing a lack of inventiveness rather than evaluating the invention at the time it was made based on objective

criteria. The Supreme Court overturned the Patent Controller's Order revoking the patent for failing to consider certain information deemed relevant by the Court. Still, the case was sent back to the Patent Controller for a *de novo* hearing within one month.

In addition, India's Patents Act requires applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent applications. These requirements may be a basis for opposition or revocation proceedings; however, the necessary relationship to the patented invention is not clear. Therefore, these requirements not only create uncertainty over potentially valuable intellectual property rights, but appear to be inconsistent with India's obligations under the TRIPS Agreement.

Conclusion

PhRMA and its member companies thank Chairman Nunes, Ranking Member Rangel, and the members of the subcommittee for holding this hearing to explore the challenges and opportunities in U.S.-India trade relations. Correcting India's protectionist IP regime will require firm leadership by the United States and we look forward to engaging further on these issues. We believe that working together with the Government of India we can ensure that patients in India and around the world will be able to benefit from our member companies' innovative therapies.